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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/857,797	09/13/2001	John Walker	017227-0175	9643
22428	7590	11/22/2005	EXAMINER	
FOLEY AND LARDNER LLP			KIM, YUNSOO	
SUITE 500			ART UNIT	
3000 K STREET NW			PAPER NUMBER	
WASHINGTON, DC 20007			1644	

DATE MAILED: 11/22/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/857,797	Applicant(s) WALKER, JOHN	
	Examiner Yunsoo Kim	Art Unit 1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 September 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 23-38 is/are pending in the application.
- 4a) Of the above claim(s) 23-38 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 23-38 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Claims 23-38 are pending.
2. Applicant's cancellation of claims 1, 4-18, 20-22 and addition of claims 24-38 in the reply filed on 9/2/05 has been acknowledged.
3. Examiner has found applicable arts while updating the search, the new ground of rejection has set forth.
4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claims 23-38 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Pat. No. 5,403,586 as is evidenced by WO 96/11711 in view of U.S. Pat. No. 6,528,058 and WO 99/02180.

The '586 patent teaches a vaccine composition comprising LHRH, saponin adjuvant and carrier suitable for human or veterinary use (claims 1, 9-10).

The '586 patent further teaches combining polymers (i.e. DEAE-dextran) and Quil-A saponin and saponin adjuvant encompasses ISCOM (col. 5- 6, overlapping paragraph lines)

As is evidenced by the '711 publication, the typical ISCOM comprises Quil-A, cholesterol, and phospholipids with the ratio of 1:1:1 and can be added to immunogen (i.e. protein, p. 2, lines 8-10).

The '586 patent does not teach specific molar ratio of DEAE-dextran to immunostimulating complex being 50-300, preferably about 125, or 10-100mg DEAE-dextran to 80-800ug of immunostimulating complex or LHRH-diphtheria toxoid conjugate.

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However the '058 patent particularly teaches the molar ratio about 50-300, the saponin component at concentration of greater than 50ug-1mg and the polycationic polyelectrolyte (i.e. DEAE-dextran) of 1 mg to 150mg (equivalent to molar ratio of 20-150, col. 4, lines 18-42, claims, claims 13-16). This range meets the economic considerations (col. 4, lines 25-28).

The '180 publication teaches that the LHRH- diphtheria toxoid (DT) conjugated are more immunogenic and effective in fertility control and LHRH has been used to control reproduction (p. 1, lines 21-26, p. 9, lines 1-6, abstract, p. 12-13 overlapping paragraph).

Therefore, one of the ordinary skill in the art would have been motivated to combine the molar ratio of saponin component to DEAE-dextran taught by the '058 patent and LHRH-DT taught by the '180 publication to the LHRH vaccine composition comprising saponin and DEAE-dextran taught by the '586 patent because the molar ratio will provide more cost effective saponin-DEAE-dextran adjuvant without compromising efficacy of adjuvant (col. 4, lines 25-28) and LHRH-DT makes better immunogen and more effective in fertility control.

From the teachings of references, it would have been obvious to one of ordinary skill in art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was prima facie obvious to one of the ordinary in the art at the time of invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

6. No claims are allowable.


7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Yunsoo Kim whose telephone number is 571-272-3176. The examiner can normally be reached on Monday thru Friday 8:30 - 5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on 571-272-0841. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Yunsoo Kim
Patent Examiner
Technology Center 1600
November 2, 2005


Patrick J. Nolan, Ph.D.
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